IN THE U.S. DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

MICHAEL AND VICKI BAILEY
2727 109th Street
Toledo, OH 43611

and

GREGORY AND DEBRA BECKER
13967 Myers Dr.
Dalton, OH 44618

and

EDWARD AND JOY CALLAN
8440 Hopewell Rd.
Cincinnati, OH 45242

and

DENNIS CONRY, AS EXECUTOR OF THE ESTATE OF JAMES CONRY, JR.
112 Sycamore Drive
Norwalk, OH 44857

and

THOMAS ENGLISH
2225 Hickory Rd. No. 9
Toledo, OH 43605

and

MELISSA FRIEDMAN, AND HER PARENTS, AMY AND MITCHELL FRIEDMAN
3136 Richmond
Beachwood, Ohio 44122

MDL Docket No. 1953

CHIEF JUDGE JAMES G. CARR
CASE NO.

Civil Action No. _____

COMPLAINT WITH JURY DEMAND ENDORSED HEREON

David W. Zoll (0008548)
Pamela A. Borgess (0072789)
ZOLL, KRANZ & BORGESS, LLC
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Counsel for Plaintiffs

)
and)
)
GARY KOTILA, AS EXECUTOR OF THE ESTATE OF BARBARA KOTILA)
208 Summit St. SW)
N. Canton, OH 44720)
)
and)
)
NANCY KUBIAK, AS ADMINISTRATRIX OF THE ESTATE OF MICHAEL YAVORSKY)
4347 Beverly Drive)
Toledo, OH 43614)
)
and)
)
IGNACIO AND PATRICIA LAHORRA, M.D.)
10 Pepperwood Lane)
Pepper Pike, Ohio 44124)
)
and)
)
KIMBERLY AND MICHAEL MCHUGH)
8504 Sandra Kay Road)
Lambertville, MI 48144)
)
and)
)
SHANNON AND MARIO PECCHIA, INDIVIDUALLY AND AS THE PARENTS AND NATURAL GUARDIANS OF SEAN PECCHIA)
724 8th Street)
Struthers, Ohio 44471)
)
and)
)
GREGORY VANWEY, AS EXECUTOR OF THE ESTATE OF LOIS VANWEY)
3258 Pontiac Section Rd.)
Monroeville, OH 44847)
)
and)

PAULINE WYSKIVER AND HER CHILDREN, JANE MCCLAIN, SUE YOUNT, CAROL HILL, AND GAIL ERHARDT
829 Evergreen Lane
Chillicothe, OH 45601

(Jane McClain)
34125 Moore Road
Logan, OH 43138

(Sue Yount)
246 E. Hocking Street
Canal Winchester, OH 43110

(Carol Hill)
4861 State Route 668 South
Junction City, OH 43748

(Gail Erhardt)
8992 Daugherty Mark Road
Hamersville, OH 45130

Plaintiffs,

v.

BAXTER HEALTHCARE CORP.; BAXTER INTERNATIONAL, INC.; SCIENTIFIC PROTEIN LABORATORIES, INC.; CHANGZHOU SPL COMPANY, LTD. **AKA KAIPU BIOCHEMCIAL CO.; AMERICAN CAPITAL LTD.; B. BRAUN MEDICAL INC.; TYCO HEALTHCARE GROUP, LP N/K/A COVIDIEN;** COVIDIEN, INC.; and MEDEFIL, INC.

Defendants.

Now come Plaintiffs, by and through the undersigned counsel, and for their Complaint hereby aver and state as follows:

THE PARTIES

1. Plaintiff MICHAEL BAILEY AND HIS SPOUSE, PLAINTIFF VICKI BAILEY, reside in the city of Toledo, Lucas County, Ohio.
2. Plaintiff GREGORY BECKER AND HIS SPOUSE, PLAINTIFF DEBRA BECKER, reside in the village of Dalton, Wayne County, Ohio.
3. Plaintiff EDWARD CALLAN AND HIS SPOUSE, PLAINTIFF JOY CALLAN, reside in the city of Cincinnati, Hamilton County, Ohio.
4. Plaintiff DENNIS CONRY resides in the city of Norwalk, Huron County, Ohio, and is or will be appointed as executor of the estate of his deceased father, JAMES CONRY, JR., who resided prior to his death in Collins, an unincorporated community in Townsend Township, Huron County, Ohio.
5. Plaintiff THOMAS ENGLISH resides in the city of Toledo, Lucas County, Ohio.
6. Plaintiff MELISSA FRIEDMAN, and her mother, Plaintiff AMY FRIEDMAN, reside in the city of Beachwood, Cuyahoga County, Ohio. Her father, Plaintiff MITCHELL FRIEDMAN resides in the city of University Heights, Cuyahoga County, Ohio.
7. Plaintiff GARY KOTILA resides in the city of N. Canton, Stark County, Ohio, and is or will be appointed as executor of the estate of his deceased mother, BARBARA KOTILA, who resided prior to her death in Ashtabula, Ashtabula County, Ohio.
8. Plaintiff NANCY KUBIAK, resides in the city of Toledo, Lucas County, Ohio, and is the Administratrix of the estate of her deceased father, Michael Yavorsky, who resided prior to his death in Toledo, Lucas County, Ohio.

9. Plaintiff IGNACIO LAHORRA, M.D. and his wife, Plaintiff PATRICIA LAHORRA, reside in the city of Pepper Pike, Cuyahoga County, Ohio

10. Plaintiff KIMBERLY MCHUGH, and her husband, MICHAEL MCHUGH, reside in the city of Lambertville, Monroe County, Michigan.

11. Plaintiffs SHANNON AND MARIO PECCHIA reside with their minor son, SEAN PECCHIA, in the city of Struthers, Mahoning County, Ohio.

12. Plaintiff GREGORY VANWEY, resides in the village of Monroeville, Huron County, Ohio, and is or will be the executor of the estate of his deceased mother, Lois VanWey, who resided prior to her death in Toledo, Lucas County, Ohio.

13. Plaintiff PAULINE WYSKIVER resides in the city of Chillicothe, Ross County, Ohio.

14. The adult children of Plaintiff Pauline Wyskiver reside in the following locations:

    A. Plaintiff JANE MCCLAIN, city of Logan, Hocking County, OH;
    B. Plaintiff SUE YOUNT, Canal Winchester, a village in Fairfield and Franklin counties, OH;
    C. Plaintiff CAROL HILL, Junction City, Perry County, OH; and
    D. Plaintiff GAIL ERHARDT, city Hamersville, Brown county, OH.

15. Defendant BAXTER HEALTHCARE CORPORATION ("Baxter Healthcare") is a corporation organized under the laws of the State of Delaware, with its principle place of business in Illinois, and is registered and authorized to do business within the State of California.

16. Defendant BAXTER INTERNATIONAL INC. is a corporation organized under the laws of the State of Delaware, with its principle place of business in Illinois.

17. Upon information and belief, Defendant Baxter Healthcare Corporation is a wholly owned subsidiary of Defendant Baxter International, Inc.

18. In engaging in the conduct alleged herein, Defendants Baxter Healthcare Corporation and Baxter International Inc. acted as the agent for each other, or Defendants' predecessors in interest.

19. For purposes of the Heparin MDL ("In Re Heparin Products Liability Litigation," MDL Docket No. 1953, Case No. 1:08-hc-60000), Amended Pretrial Order Number 5, Kirkland & Ellis, LLP shall accept service of process on behalf of Defendants Baxter Healthcare Corporation and Baxter International Inc. (herein collectively referred to as "Baxter"), Scientific Protein Laboratories LLC ("SPL"), Changzhou SPL Co. ("CZSPL"), and American Capital Ltd. ("ACAS"), by sending a copy of this document along with a request for waiver of service, under Rule 4 of the Federal Rules of Civil Procedure to Nora Shea, Senior Legal Assistant, Kirkland & Ellis, LLP, 200 E. Randolph Drive, Chicago, Illinois 60302.

20. At all times relevant, Defendant Baxter was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of California, either directly or indirectly through third parties or related entities, the prescription drug heparin sodium ("heparin") in varying products, dosages and quantities.

21. Defendant B. BRAUN MEDICAL INC., ("B. Braun"), is a corporation organized under the laws of the State of Pennsylvania with its principal place of business in Pennsylvania and is registered and authorized to do business within the State of California.

22. At all times relevant, Defendant B. Braun was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of California, either directly or indirectly through third parties or related entities, the prescription drug heparin sodium ("heparin") in varying products, dosages and quantities.

23. For purposes of the Heparin MDL ("In Re Heparin Products Liability Litigation," MDL Docket No. 1953, Case No. 1:08-hc-60000), Amended Pretrial Order Number 5,

Rohrbachers Cron Manahan Trimble & Zimmerman, Co., L.P.A shall accept service of process on behalf of Defendant B. Braun by sending a copy of this complaint along with a request for waiver of service under Rule 4 of the Federal Rules of Civil Procedure to Matthew J. Rohrbacher at Rohrbachers Cron Manahan Trimble & Zimmerman, Co., L.P.A.

24. Defendant TYCO HEALTHCARE GROUP LP n/k/a COVIDIEN and Defendant COVIDIEN, INC., (herein collectively referred to as "Covidien") are Delaware corporations with their United States headquarters at 15 Hampshire Street, Mansfield, Massachusetts 02048.

25. At all times relevant, Defendant Covidien was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of California, either directly or indirectly through third parties or related entities, the prescription drug heparin sodium ("heparin") in varying products, dosages and quantities.

26. For purposes of the Heparin MDL ("In Re Heparin Products Liability Litigation," MDL Docket No. 1953, Case No. 1:08-hc-60000), Amended Pretrial Order Number 5, Shook, Hardy & Bacon shall accept service of process on behalf of Defendant Covidien by sending a copy of this complaint along with a request for waiver of service under Rule 4 of the Federal Rules of Civil Procedure to Michael D. Moeller at Shook, Hardy & Bacon.

27. Defendant MEDEFIL, INC., ("Medefil"), is a corporation organized under the laws of the State of Illinois with its principal place of business in Illinois.

28. At all times relevant, Defendant Medefil was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of California, either directly or indirectly through third parties or related entities, the prescription drug heparin sodium ("heparin") in varying products, dosages and quantities.

29. For purposes of the Heparin MDL ("In Re Heparin Products Liability Litigation," MDL Docket No. 1953, Case No. 1:08-hc-60000), Amended Pretrial Order Number 5, Seeley, Savidge, Ebert & Gourash Co., LPA shall accept service of process on behalf of Defendant Medefil by sending a copy of this complaint along with a request for waiver of service under Rule 4 of the Federal Rules of Civil Procedure to Daniel F. Gourash at Seeley, Savidge, Ebert & Gourash Co., LPA.

30. Defendant SCIENTIFIC PROTEIN LABORATORIES, LLC, ("SPL") is a corporation organized under the laws of the State of Delaware, with its principle place of business in Waunakee, Wisconsin.

31. Defendant AMERICAN CAPITAL LTD., (herein "American Capital"), formerly American Capital Strategies, Ltd., is a corporation organized under the laws of the State of Delaware, with its principal place of business in Maryland.

32. Defendant SPL is majority-owned by Defendant American Capital.

33. In engaging in the conduct alleged herein, Defendants SPL and American Capital Ltd. acted as the agent for each other, or Defendants' predecessors in interest.

34. At all times relevant, SPL was engaged in the business of developing, manufacturing, promoting, marketing, distributing, testing, warranting, supplying, selling and/or introducing into interstate commerce, including in the State of California, component ingredients to pharmaceutical, veterinary and food industries. These component ingredients include active pharmaceutical ingredients ("API") such as crude heparin, Heparin Sodium USP,[1] and heparin lithium API.

35. These APIs are used in the production and manufacturing of the prescription drug, heparin.

[1] USP stands for United States Pharmacopeia and is one of the measurement systems used for pharmaceutical products.

36. At all times relevant, SPL supplied the APIs for the recalled heparin manufactured by Defendants Baxter, B. Braun, Covidien and Medefil.

37. Defendant CHANGZHOU SPL COMPANY, LTD. ("CZ-SPL"), also known as Kaipu Biochemical Co., is a joint venture between SPL and Techpool Bio-Pharma Co., Ltd. ("Techpool"), operating a heparin API manufacturing facility located in Jiangsu Province, China.

38. Upon information and belief, SPL has a majority interest of 55% and management oversight for CZ-SPL and its manufacturing facility.

39. In engaging in the conduct alleged herein, Defendants SPL and CZ-SPL acted as the agent for each other, or Defendants' predecessors in interest.

40. At all times relevant, CZ-SPL was engaged in the business of manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, component ingredients, particularly APIs such as crude heparin, heparin sodium USP, and heparin lithium API, to various pharmaceutical companies, including, but not limited to, SPL.

41. At all times relevant, CZ-SPL supplied the APIs for the recalled heparin manufactured by Defendants Baxter, B. Braun, Covidien and Medefil.

42. At all times relevant, SPL supplied the APIs for the heparin administered to Plaintiffs' decedent.

43. American Capital and SPL have dissolved or otherwise terminated CZ-SPL and have assumed its assets and liabilities.

44. Baxter and SPL have entered into a settlement agreement / supply agreement, pursuant to which they have agreed to jointly share the costs of any and all compensatory judgments, as well as other litigation expenses and to cooperate in the common defense of this claim.

45. As a result, the Defendants Baxter and SPL should be held jointly and severally liable, without regard to any statute or rule which would otherwise require the assessment or allocation of responsibility or liability.

JURISDICTION AND VENUE

46. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. §1332, as there is complete diversity of citizenship between Plaintiffs and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

47. Direct filing of this action in the Northern District of Ohio, Western Division, is appropriate pursuant to Pretrial Order No. 1, which authorizes any plaintiff whose case would be subject to transfer to the Northern District of Ohio, Master Docket ("In re Heparin Products Liability Litigation," MDL Docket No. 1953, Case No. 1:08-hc-60000) to file directly in this district.

48. Venue for Plaintiffs MICHAEL AND VICKI BAILEY is appropriate in this district and division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in this division and district and Defendants conduct business, reside and are subject to personal jurisdiction here.

49. Venue on remand for Plaintiffs GREGORY AND VICKI BECKER from Heparin MDL No. 1953 proceedings is appropriate in the Eastern Division of the Northern District of Ohio, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in that division and district and Defendants conduct business, reside and are subject to personal jurisdiction there.

50. Venue on remand for Plaintiffs EDWARD AND JOY CALLAN from Heparin MDL No. 1953 proceedings is appropriate in the Southern District of Ohio, Western Division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in

that division and district and Defendants conduct business, reside and are subject to personal jurisdiction there.

51. Venue for Plaintiff DENNIS CONRY, AS EXECUTOR OF THE ESTATE OF JAMES CONRY, JR. is appropriate in this district and division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in this division and district and Defendants conduct business, reside and are subject to personal jurisdiction here.

52. Venue for Plaintiff THOMAS ENGLISH is appropriate in this district and division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in this division and district and Defendants conduct business, reside and are subject to personal jurisdiction here.

53. Venue on remand for Plaintiffs MELISSA, AMY AND MITCHELL FRIEDMAN from Heparin MDL No. 1953 proceedings is appropriate in the Eastern Division of the Northern District of Ohio, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in that division and district and Defendants conduct business, reside and are subject to personal jurisdiction there.

54. Venue on remand for Plaintiff GARY KOTILA, AS EXECUTOR OF THE ESTATE OF BARBARA KOTILA, from Heparin MDL No. 1953 proceedings is appropriate in the Eastern Division of the Northern District of Ohio, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in that division and district and Defendants conduct business, reside and are subject to personal jurisdiction there.

55. Venue for Plaintiff NANCY KUBIAK, AS ADMINISTRATRIX OF THE ESTATE OF MICHAEL YAVORSKY is appropriate in this district and division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in this division and district and Defendants conduct business, reside and are subject to personal jurisdiction here.

56. Venue on remand for Plaintiffs IGNACIO AND PATRICIA LAHORRA, from Heparin MDL No. 1953 proceedings is appropriate in the Eastern Division of the Northern District of Ohio, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in that division and district and Defendants conduct business, reside and are subject to personal jurisdiction there.

57. Venue for Plaintiffs KIMBERLY AND MICHAEL MCHUGH is appropriate in this district and division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in this division and district and Defendants conduct business, reside and are subject to personal jurisdiction here.

58. Venue on remand for Plaintiffs SHANNON AND MARIO PECCHIA, individually and as the parents and natural guardian of SEAN PECCHIA, from Heparin MDL No. 1953 proceedings is appropriate in the Eastern Division of the Northern District of Ohio, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in that division and district and Defendants conduct business, reside and are subject to personal jurisdiction there.

59. Venue for Plaintiff GREGORY VANWEY, AS EXECUTOR OF THE ESTATE OF LOIS VANWEY is appropriate in this district and division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in this division and district and Defendants conduct business, reside and are subject to personal jurisdiction here.

60. Venue on remand for Plaintiff PAULINE WYSKIVER from Heparin MDL No. 1953 proceedings is appropriate in the Southern District of Ohio, Eastern Division, pursuant to 28 U.S.C. 1391 because a substantial part of the events giving rise to this claim occurred in that division and district and Defendants conduct business, reside and are subject to personal jurisdiction there.

FACTS

61. Heparin is a prescription drug in a class of medications called anticoagulants, also known as blood thinners.

62. Heparin is one of the oldest drugs currently still in widespread clinical use, having been used since the early 1900s.

63. Heparin works by decreasing the clotting ability of the blood, thereby preventing the actual formation of clots or preventing the extension of existing clots within the blood.

64. Heparin is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters such as in kidney dialysis, and for other such conditions like pulmonary emboli.

65. Heparin is packaged for individual or multiple dose use, in vial form, pre-filled form, and pre-mixed intravenous bag form.

66. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

67. Heparin is a glycosaminoglycan extracted from pig (porcine) intestines.

68. The intestines of approximately 3,500 pigs are required to produce approximately 2.2 pounds of crude heparin.

69. Crude heparin is processed to remove impurities and results in the production of an API such as Heparin Sodium or Heparin Lithium. This processing includes, but is not limited to, fractional precipitation, purification, and chemical treatment.

Baxter

70. Baxter is one of the largest producers of heparin in the United States, and its sales of heparin constitute at least a 50% market share.

71. Baxter sells an estimated 35 million units of heparin per year, with annual sales of approximately $30 million dollars.

72. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced from products in market-leading positions.

73. Baxter manufactures products in 26 countries and sells them in more than 100 countries.

74. Baxter purchases the raw materials essential to its business, including heparin API, from multiple suppliers worldwide, including Defendant SPL.

75. Although it sold contaminated heparin, Defendant Baxter expressly and impliedly represented to Decedent, the medical community and the public that each of its heparin products were safe and effective for their intended use, and that its heparin prescription products in fact did actually contain pure heparin.

76. Baxter also represented the following to Plaintiffs' decedent, his healthcare providers and the public:

    a. That it "places a significant emphasis on providing quality products and services to its customers."

    b. That in "an effort to manage risks associated with raw materials supply, Baxter works closely with its suppliers to ensure availability and continuity of supply while maintaining high quality and reliability;"

    c. That "great care is taken in assuring the safety of raw materials;"

    d. That it "regularly reviews its quality systems to determine their effectiveness and identify areas for improvement."

    e. That it "performs assessments of its suppliers of raw materials, components and finished goods."

    f. That the "operations of Baxter and many of the products manufactured or sold by the company are subject to extensive regulation by numerous governmental agencies, both within and outside the United States."

B. Braun

77. Defendant B. Braun purchases the raw material essential to its business, including heparin API, from multiple suppliers worldwide, including Defendant SPL.

78. Although it sold contaminated heparin, Defendant B. Braun represented to Decedent, the medical community and the public that each of its heparin products were safe and effective for their intended use, and that its heparin prescription products in fact did actually contain heparin, rather than a synthetic contaminant.

79. Defendant B. Braun also warranted and represented to the public that it used "state-of-the-art manufacturing capabilities," and that it adhered to the highest standards in safety and quality.

Covidien

80. Defendant Covidien purchases the raw material essential to its business, including heparin API, from multiple suppliers worldwide, including Defendant SPL.

81. Although it sold contaminated heparin, Defendant Covidien represented to Decedent, the medical community and the public that each of its heparin products were safe and effective for their intended use, and that its heparin prescription products in fact did actually contain heparin, rather than a synthetic contaminant.

82. Defendant Covidien also warranted and represented the following to the public:

    a. That it "works closely with its suppliers to help ensure availability and continuity of supply while maintaining high quality and reliability."

    b. That its production processes employing those materials "adequately eliminates inactive infections or toxic elements that may be present in these raw materials."

    c. That it places significant emphasis on providing quality products and services to its customers.

    d. That its quality management plays an essential role in determining and meeting customer requirements, preventing defects and improving the company's products and services.

e. That it has a network of quality systems throughout its business units and facilities which relate to the design, development, manufacturing, packaging, sterilization, handling, distribution and labeling of the company's products.

f. That in order to assess and facilitate compliance with applicable requirements, it regularly reviews its quality systems to determine their effectiveness and identify areas of improvement, and that it "performs assessments of its suppliers of raw materials, components and finished goods."

g. That its "operations…and many of the products manufactured or sold by the company are subject to extensive regulation by numerous governmental agencies, both within and outside the United States." According to Defendant Covidien, such agencies include the United States Food and Drug Administration ("FDA"), among others.

Medefil

83. Although it sold contaminated heparin, Defendant Medefil represented to Decedent, the medical community and the public that each of its heparin products were safe and effective for their intended use, and that its heparin prescription products in fact did actually contain heparin, rather than a synthetic contaminant.

84. Defendant Medefil also warranted and represented to the public that it adhered to the highest standards in safety and quality.

85. Defendant Medefil purchases the raw material essential to its business, including heparin API, from multiple suppliers worldwide, including Defendant SPL.

SPL and CZ-SPL

86. China is now the world's largest producer of APIs, having an estimated $4.4 billion dollar market share, and its production accounts for an estimated 22% of the foreign factories producing drugs for the U.S. market.

87. CZ-SPL is the sixth largest exporter in China of heparin ingredients by volume for 2007.

88. Although they sold contaminated heparin API, Defendant SPL and its parent company, Defendant American Capital LTD., represented to Decedent, the medical community and the public that their heparin API product was safe and effective for its intended use, that

their heparin API met USP requirements and that their heparin API actually contained pure pharmaceutical grade heparin.

89. Defendant SPL also represented the following to Plaintiffs' decedent, his healthcare providers and the public:

a. That its "experience and know-how in commercial-scale production of active pharmaceutical ingredients from biological sources, together with its expertise in analytical testing, quality assurance, and regulatory affairs, is the backbone for [its] contract development and cGMP manufacturing services."

b. That its "contract manufacture sector is staffed by knowledgeable and experienced R&D scientists and process engineers, operating in a state-of-the-art cGMP facility with capabilities in natural products extraction, fermentation, and purification."

c. That it "is committed to providing high quality contract development and manufacturing services…"

d. That it has the capability to "establish specific cGMP process guidelines and control conditions."

e. That it "utilizes both conventional and state-of-the-art methods for recovery and purification of recombinant microbial products as well as extracted natural products."

f. That its "recovery and purification facility includes cGMP compliant, solvent-capable, Class 10,000 clean rooms."

g. That its "quality control and microbiology laboratories are fully validated."

h. That "SPL's quality control and microbiology laboratories are fully validated. We utilize numerous standard and compendial methods for in-process and release testing of drug products. We also have the capability to develop, qualify, and validate a wide range of non-compendial analytical test methods."

i. That its "facilities are operated strictly in accordance with FDA's cGMP requirements. We have an experienced and dedicated quality assurance and regulatory staff committed to providing complete regulatory support to our customers and maintaining the highest quality standards for our commercial products and contract manufacturing services."

j. That "SPL is regularly inspected by multiple regulatory agencies such as the FDA and USDA and participates in many annual customer audits. We maintain a stellar regulatory inspection record by doing things right the first time and maintain that commitment to excellence every day of the year."

k. That "SPL has gone to great lengths to ensure that consistency in compliance is maintained at both of our global manufacturing sites in Waunakee, WI and Changzhou, China. We rigorously apply the same work processes, documentation requirements and QA/QC regimen at both facilities to provide our customers with the reliability and peace of mind they value no matter where SPL products are sourced around the world. FDA-approved APIs from both sites are supported by an ever-expanding list of Drug Master Files, Import Certificates, EU Certificates of Compliance and other documentation that makes sourcing APIs through SPL simple and worry-free."

90. Despite its warranties, the CZ-SPL facility in China was never inspected by the U.S. FDA until after the recall of Baxter's heparin in 2008, despite the fact the regulations require inspections of foreign facilities importing into the United States.

91. The International Compliance Team for the U.S. FDA performed an inspection of the CZ-SPL facility from February 20 – 26, 2008.

92. Upon information and belief, CZ-SPL did not have a license from China's State Food and Drug Administration agency as a pharmaceutical manufacturer.

93. Defendant CZ-SPL is believed to obtain its crude heparin from at least two Chinese wholesale suppliers, who in turn obtain the crude heparin from multiple small family-owned workshops that process or extract the crude heparin.

94. Despite representations that these workshops are audited or inspected, it is believed that many of these workshops have never been inspected by either the wholesaler, CZ-SPL, or any representative of any regulatory agency in China or otherwise.

95. The partially redacted report of the inspection establishes severe deficiencies in CZ-SPL's manufacturing processes. More specifically, the inspectors made the following observations:

a. There have been no critical processing steps identified for the Heparin Sodium USP **[Redacted]** process, and, the repeated and efficient removal of impurities, such as proteins, nucleotides, virus, endotoxin, bacteria and heavy metals at the appropriate, specified, process steps has not been evaluated. There was no report for annual **[Redacted]** test results available.

The improvements offered by removal of a raw material **[Redacted]** test **[Redacted]** a batch size increase, an added **[Redacted]** step, a change in **[Redacted]** for the **[Redacted]** step and **[Redacted]** and parameter changes, approved in a 1/05 process validation report for Heparin Sodium USP, were not demonstrated.

b. There has been no impurity profile established for Heparin Sodium USP and no evaluation for degradants during stability program testing.

c. The manufacturing instructions for Heparin Sodium USP are incomplete in that they do not include a description of manual manipulations of the **[Redacted]** during processing steps, they do not include the actual, manually entered **[Redacted]** set temperatures and times and, operator observations such as level measurements, used in calculations, during the **[Redacted]** step are not recorded.

d. There has been no test method verification performed for the reported USP test methods, Nitrogen Determination, Protein and Total Aerobic Microbial Count, employed in testing of Heparin Sodium USP and Heparin Crude materials, to show that the methods are suitable under actual conditions of use. In addition, there is no routine test for **[Redacted]** residue amount at the time of release.

e. Investigations into failed lots and out of trend lots were approved as complete, but did not identify a cause for the problem. For example,

Heparin Sodium USP batch **[Redacted]** failed the Nitrogen Determination test and was reprocessed to make **[Redacted]** without finding the reason for the slightly high, OOS Nitrogen result.

Investigations into [**Handwritten #2: cross out a word, added "OOT"**] of customer **[Redacted]** specification **[Redacted]** for Heparin Sodium USP lots [**Handwritten #3: cross out word(s)**] **[Redacted]** and **[Handwritten #4: cross out word.]** were performed without knowing what the failed test measurement actually represented.

[Redacted][Handwritten #5: added "and the failure of lot"][Redacted]

Investigations into ROI out of trend results for Heparin Sodium USP lots **[Redacted]** identified both results inappropriately as outliers.

f. Heparin Crude lots **[Redacted]** received 8/06 from vendor **[Handwritten #6: cross out word(s)] [Redacted]** that included material from an unacceptable workshop vendor were used in Heparin Sodium USP **[Redacted]** marketed to the USA. In addition, prior to 3/06 there are no **[Redacted]** records from vendor **[Redacted]** showing the source for their crude materials.

g. The inside surface of large, "cleaned" **[Redacted]** tanks used in the final **[Redacted]** step, after both **[Redacted]** were very scratched, with unidentified material adhering to the insides and, the inverted handles held liquid, which spilled to the bottom of the tank when it was uprighted. There was no written procedure showing that the tanks were dedicated to a particular process step. There was no data collected to verify marker and tape volume markings on the outside of the tanks and, the cleaning method was not validated. It was noted that equipment cleaning tags were made of paper and taped to the piece of equipment unprotected from liquids used in the processing room environments.

h. Raw material inventory records were incomplete in that samples removed from the containers and the status and amount of materials returned from use by the production processing department were not recorded. For **[Redacted]** stored in a freezer, the amount, condition and date of return was not recorded.

i. Control of material flow in the processing area was inadequate in that waste **[Redacted]** was carted through a door to the outside in the processing area and not provided for by the material flow written procedure.

j. The outer foil bags containing Heparin Sodium USP lot **[Redacted]** manufactured and held since 5/25/07, are not labeled. The drum lid showed the only indications of the lot number.

k. There is no report or data to show that leachables for the **[Redacted]** bags used to hold Heparin Sodium USP lot, have been evaluated.

96. The report establishes insufficient quality and safety controls and violations of the cGMP regulations.

97. In fact, the report itself even references a specific instance where heparin crude lots received from a vendor and included material from an unacceptable workshop vendor. Yet, this material was still used in Heparin Sodium USP marketed to the United States.

98. Since the commencement of this litigation, SPL, with the knowledge and consent of Baxter and the full participation and involvement of American Capital, has dissolved CZ-SPL, sold its assets, and destroyed its records, with the purpose and / or effect of avoiding liability for the contamination.

99. SPL, with the full knowledge and consent of American Capital and Baxter, entered into a joint venture agreement with Techpool, a Chinese company, and relied upon Techpool for the supply of crude heparin.

100. SPL and Baxter knew or should have known that Techpool would not consent to inspection, supervision, oversight or review.

101. Techpool and the other consolidators of crude heparin from whom SPL or CZ-SPL purchased crude are beyond the jurisdiction of this Court, or any court, and are not subject to deposition or discovery.

All Defendants

102. Defendants' Heparin and its API were represented by them to be safe and effective for their intended uses, including, but not limited to, incorporation as an API into heparin and the intravenous administration of heparin during hemodialysis and other medical procedures.

103. The heparin products sold by Defendants and/or the API used in their manufacture were defective in their manufacture.

104. Upon information and belief, Defendants did not meet the requisite requirements for importation and/or sale of APIs within the United States.

105. Such requirements include, but are not necessarily limited to, inspection and approval by the FDA.

106. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval.

107. Defendants' heparin, including its API, was defective at the time it was placed in the stream of commerce.

108. Defendants knew or should have known that these products were defective at the time the products left their respective control and custody.

109. Defendants also knew or should have known that the heparin products were causing adverse reactions for patients, such as Plaintiffs' Decedent.

110. Notwithstanding their knowledge, Defendants continued to supply and sell the heparin products up to and until just recently, without providing any warnings about the risks and dangers associated with the heparin products to members of the public and the medical community, including Decedent.

111. At all material times, Defendants intentionally concealed from the public and members of the medical community, including Decedent, the risks and dangers associated with the use of the heparin products, and their API, and/or has misrepresented the safety, quality and performance of the heparin products.

112. On or about January 17, 2008, Defendant Baxter began recalling nine lots of Heparin Sodium Injection multiple-dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials, and 10,000 units/mL for 4mL vials.

113. Baxter announced this recall on January 25, 2008.

114. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

115. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pain, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimuli, as well as cases of severe hypotension requiring treatment.

116. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

117. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

118. According to the FDA, as of April 8, 2008, there have been 103 reports of death in patients receiving heparin since January 1, 2007, with 91 of said deaths reported to the FDA on or after January 1, 2008. Out of the 103 reported deaths, 62 of the reports of death included one or more allergic symptom(s) or symptoms of hypotension, with 56 of said deaths reported to the FDA on or after January 1, 2008.

119. This number of adverse reports represents a significant increase in reported adverse events associated with the use of Heparin. For example, in 2006 there were 55 reports of death in patients receiving heparin from January 1, 2006 to December 31, 2006, with three (3) of said reports including one or more allergic symptom(s) or symptoms of hypotension.

120. Based upon the clusters of adverse reports, Defendant Baxter and the Center for Disease Control ("CDC") initially identified nine specific heparin manufacturing lots with a suggested link to these cases.

121. The initial nine lots recalled by Defendant Baxter are for the following heparin products: NDC# 00641-2440-45, NDC# 00641-2440-41, NDC# 00641-2450-45, and NDC# 00641-2450-41. The products include the following lots:

    a. Heparin 1000 units/mL, 10 mL vial, expiration date 10/2009, Lot #107054
    b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
    c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
    d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
    e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
    f. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107064
    g. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107066
    h. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107074
    i. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107111

122. Upon information and belief, the active pharmaceutical ingredient in these products was provided by Defendants SPL and CZ-SPL.

123. As of February 11, 2008, Defendant Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and incidents of hypotension that are being reported.

124. On February 28, 2008, Defendant Baxter and the FDA issued additional press releases indicating Baxter was expanding its recall to include all remaining lots and doses of its multiple-dose vials, single dose vials, and HEP-LOCK heparin flush products.

125. This recall included the remaining lots of those products and heparin sodium injection 5000 units/mL 10mL multi-dose vials, heparin sodium injection 10,000 units/mL 4mL multi-dose vials, heparin sodium injection 1000 USP units/mL, 5000 USP units/mL, and 10,000 USP units/mL single-dose vials, and all HEP-LOCK and HEP-LOCK U/P, 10 USP units/mL and 100 USP units/mL vials, both preserved and preservative-free.

126. On March 20, 2008, Defendant Medefil recalled 3,151,080 heparin I.V. flush syringes after being notified that at least one lot of heparin API provided by Defendant SPL and CZ-SPL was contaminated.

127. On March 21, 2008, Defendant B. Braun recalled 23 lots heparin solution it manufactured and distributed nationwide after being notified that at least one lot of heparin API provided by Defendant SPL and CZ-SPL was contaminated.

128. On March 28, 2008 Defendant Covidien recalled 32 lots of pre-filled syringes containing heparin after being notified that at least two lots of heparin API provided by Defendants SPL and CZ-SPL were contaminated.

129. The FDA announced on March 19, 2008, that it had identified the contaminant as over-sulfated chondroitin sulfate.

130. Over-sulfated chondroitin sulfate is a glycosaminoglycan that is not an approved drug in the U.S.

131. Ordinary chondroitin sulfate is a biologically-derived glycosaminoglycan.

132. Chondroitin Sulfate must be chemically modified to create over-sulfated chondroitin sulfate.

133. The FDA reports there is no known intravenous use for this chemical compound.

134. The over-sulfated chondroitin sulfate was specifically identified in many samples of heparin API that were collected from Changzhou SPL in China.

135. The over-sulfated chondroitin sulfate was identified in many of the recalled lots associated with adverse drug reactions.

136. According to the FDA, the contaminant found in Defendants' heparin, over-sulfated chondroitin sulfate ("OSCS"), was present in significant quantities, accounting for 5 to 20 percent of the total mass of each sample tested.

137. In addition to OSCS, Defendants' heparin contained other glycosaminoglycan contaminants, including, but not limited to, dermatan sulfate ("DS"), heparan sulfate ("HS") and various other oversulfated glycosaminoglycans.

138. To date, Defendants have still been unable to identify all of the contaminants found in Defendants' heparin.

139. All of the identified contaminants found in Defendants' heparin consist either of glycosaminoglycan molecules found in the byproduct produced during the manufacture of heparin from heparin crude, such as DS, or of glycosaminoglycan molecules found in the byproduct produced during the manufacture of heparin from heparin crude that have been subjected to sulfonation, such as OSCS.

140. As a direct and proximate result of Defendants' defective heparin products and/or the API used in these products, Plaintiffs and Plaintiffs' Decedent have been injured and incurred substantial damages, including, but not limited to, the death of the Decedent, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

141. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

FACTS REGARDING PLAINTIFF MICHAEL BAILEY

142. At the end of 2007 and 2008, Plaintiff Michael Bailey was administered heparin during hemodialysis at Fresenius Central Dialysis, in Toledo, Ohio.

143. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff was a contaminated heparin product manufactured by one or more Defendants.

144. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

145. As a direct and proximate cause of the defective heparin being administered to him, and the attendant medical symptoms and severe injury he then suffered, Plaintiffs Michael and

Vicki Bailey have incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium and/or other damages for which Defendants are liable.

146. At the time of his injuries, Plaintiffs were not aware that the heparin that Plaintiff Gregory Becker received was contaminated, that it resulted in his injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFF GREGORY BECKER

147. In approximately February 2008, Gregory Becker was administered heparin while hospitalized at Aultman Hospital in Canton, Ohio.

148. Upon information and belief, on at least one occasion, the heparin administered to Gregory Becker was a contaminated heparin product manufactured by one or more Defendants.

149. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

150. As a direct and proximate cause of the defective heparin being administered to him, and the attendant medical symptoms and severe injury he then suffered, Plaintiffs Michael and Vicki Bailey have incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium and/or other damages for which Defendants are liable.

151. At the time of his injuries, Plaintiffs were not aware that the heparin that Plaintiff Gregory Becker received was contaminated, that it resulted in his injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFF EDWARD CALLAN

152. In approximately February 2008, Edward Callan was administered heparin while undergoing medical treatment at The Christ Hospital in Cincinnati, Ohio.

153. Upon information and belief, on at least one occasion, the heparin administered to Edward Callan was a contaminated heparin product manufactured by one or more Defendants.

154. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

155. As a direct and proximate cause of the defective heparin being administered to him, and the attendant medical symptoms and severe injury he then suffered, Plaintiffs Edward and Joy Callan have incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium and/or other damages for which Defendants are liable.

156. At the time of his injuries, Plaintiffs were not aware that the heparin that Edward Callan received was contaminated, that it resulted in his injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING DECEDENT JAMES CONRY, JR.

157. Plaintiff’s Decedent, James Conry, Jr. died on December 25, 2007.

158. Shortly before his death, Plaintiff’s Decedent was administered heparin while admitted at Fisher Titus Memorial Hospital in Norwalk, Ohio.

159. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff’s Decedent was a contaminated heparin product manufactured by one or more Defendants.

160. Shortly thereafter, the Decedent began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

161. As a direct and proximate cause of the defective heparin being administered to him, and the attendant medical symptoms he then suffered, Decedent died on December 25, 2007.

162. As a direct and proximate result of this defective product Plaintiff's Decedent has also been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium and other damages for which Defendants are liable.

163. At the time of his death, Plaintiff's Decedent and Plaintiff were not aware that the heparin Plaintiff's Decedent received was contaminated, that it resulted in his injuries and death, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such.

164. Plaintiff and Plaintiff's Decedent did not discover, nor did they have reason to discover, that the heparin that Plaintiff's Decedent was given was contaminated and/or that Defendants' failures described herein resulted in his injuries and ultimately, death, until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFF THOMAS ENGLISH

165. In 2007 and 2008, Plaintiff Thomas English was administered heparin during hemodialysis at Fresenius Dialysis on Laskey Road, in Toledo, Ohio.

166. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff was a contaminated heparin product manufactured by one or more Defendants.

167. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

168. As a direct and proximate cause of the defective heparin being administered to him, and the attendant medical symptoms and severe injury he then suffered, Plaintiff Thomas English has incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, and/or other damages for which Defendants are liable.

169. At the time of his injuries, Plaintiff Thomas English was not aware that the heparin that he received was contaminated, that it resulted in his injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiff have any reason to know of such until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFF MELISSA FRIEDMAN

170. In approximately March of 2008, Plaintiff Melissa Friedman was administered heparin while at Rainbow Babies and Children's Hospital in Cleveland, Ohio.

171. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff Melissa Friedman was a contaminated heparin product manufactured by one or more Defendants.

172. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

173. As a direct and proximate cause of the defective heparin being administered to her, and the attendant medical symptoms and severe injury she then suffered, Plaintiff Melissa Friedman, and her parents, Plaintiffs Amy and Mitchell Friedman, have incurred additional

damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium and/or other damages for which Defendants are liable.

174. At the time of her injuries, Plaintiffs were not aware that the heparin that Plaintiff Melissa Friedman received was contaminated, that it resulted in her injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after Plaintiff's reaction and the multiple recalls by Baxter in 2008.

FACTS REGARDING DECEDENT BARBARA KOTILA

175. Plaintiff's Decedent, Barbara Kotila died on November 11, 2007.

176. Shortly before her death, Plaintiff's Decedent was administered heparin while admitted at the Cleveland Clinic in Cleveland, Ohio.

177. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff's Decedent was a contaminated heparin product manufactured by one or more Defendants.

178. Shortly thereafter, the Decedent began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

179. As a direct and proximate cause of the defective heparin being administered to her, and the attendant medical symptoms she then suffered, Decedent died on November 11, 2007.

180. As a direct and proximate result of this defective product Plaintiff's Decedent has also been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium, and other damages for which Defendants are liable.

181. At the time of her death, Plaintiff's Decedent and Plaintiff were not aware that the heparin Plaintiff's Decedent received was contaminated, that it resulted in her injuries and death, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such.

182. Plaintiff and Plaintiff's Decedent did not discover, nor did they have reason to discover, that the heparin that Plaintiff's Decedent was given was contaminated and/or that Defendants' failures described herein resulted in her injuries and ultimately, death, until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING DECEDENT MICHAEL YAVORSKY

183. Plaintiff's Decedent, Michael Yavorsky died on March 7, 2008.

184. Shortly before his death, Plaintiff's Decedent was administered heparin during hemodialysis at Wildwood Dialysis in Toledo, Ohio.

185. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff's Decedent was a contaminated heparin product manufactured by one or more Defendants.

186. Shortly thereafter, the Decedent began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

187. As a direct and proximate cause of the defective heparin being administered to him, and the attendant medical symptoms he then suffered, Decedent died on March 7, 2008.

188. As a direct and proximate result of this defective product Plaintiff's Decedent has also been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium, and other damages for which Defendants are liable.

189. At the time of his death, Plaintiff's Decedent and Plaintiff were not aware that the heparin Plaintiff's Decedent received was contaminated, that it resulted in his injuries and death, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such.

190. Plaintiff and Plaintiff's Decedent did not discover, nor did they have reason to discover, that the heparin that Plaintiff's Decedent was given was contaminated and/or that Defendants' failures described herein resulted in his injuries and ultimately, death, until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFF IGNACIO LAHORRA, M.D.

191. In approximately January, 2008, Plaintiff Ignacio Lahorra, M.D. was administered heparin while undergoing medical treatment at Hillcrest Hospital in Mayfield Heights, Ohio.

192. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff Ignacio Lahorra, M.D. was a contaminated heparin product manufactured by one or more Defendants.

193. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

194. As a direct and proximate cause of the defective heparin being administered to him, and the attendant medical symptoms and severe injury he then suffered, Plaintiffs Ignacio and Patricia Lahorra have incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium, and/or other damages for which Defendants are liable.

195. At the time of his injuries, Plaintiffs were not aware that the heparin that Plaintiff Ignacio Lahorra received was contaminated, that it resulted in his injuries, and that said

contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFF KIMBERLY MCHUGH

196. In approximately February of 2008, Plaintiff Kimberly McHugh was administered heparin while at Flower Hospital in Sylvania, Ohio.

197. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff Kimberly McHugh was a contaminated heparin product manufactured by one or more Defendants.

198. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

199. As a direct and proximate cause of the defective heparin being administered to Plaintiff Kimberly McHugh, and the attendant medical symptoms and severe injury she then suffered, Plaintiffs Kimberly and Michael McHugh have incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium, and/or other damages for which Defendants are liable.

200. At the time of her injuries, Plaintiffs were not aware that the heparin that Plaintiff Kimberly McHugh received was contaminated, that it resulted in her injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after Plaintiff’s reaction and the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFFS SHANNON PECCHIA AND SEAN PECCHIA

201. At the end of 2007 and early 2008, Plaintiff Shannon Pecchia, who was pregnant with Sean Pecchia, took heparin purchased from Walgreens in Poland, Ohio.

202. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff Shannon Pecchia was a contaminated heparin product manufactured by one or more Defendants.

203. Shortly thereafter, the Plaintiff began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

204. As a direct and proximate cause of the defective heparin being administered to Plaintiff Shannon Pecchia and the attendant medical symptoms and severe injury she then suffered, Sean Pecchia was born prematurely on February 1, 2008, and Plaintiffs have incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium, and/or other damages for which Defendants are liable.

205. At the time of her injuries, Plaintiffs were not aware that the heparin that Plaintiff Shannon Pecchia received was contaminated, that it resulted in her and Sean's injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after Plaintiff's reaction and the multiple recalls by Baxter in 2008.

FACTS REGARDING DECEDENT LOIS VANWEY

206. Plaintiff's Decedent, Lois VanWey died on November 19, 2007.

207. Shortly before her death, Plaintiff's Decedent was administered heparin during dialysis at Dialysis Partners of Northwest Ohio located in Toledo, Ohio.

208. Upon information and belief, on at least one occasion, the heparin administered to Plaintiff's Decedent was a contaminated heparin product manufactured by one or more Defendants.

209. Shortly thereafter, the Decedent began to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

210. As a direct and proximate cause of the defective heparin being administered to her, and the attendant medical symptoms she then suffered, Decedent died on November 19, 2007.

211. As a direct and proximate result of this defective product Plaintiff's Decedent has also been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, loss of consortium, and other damages for which Defendants are liable.

212. At the time of her death, Plaintiff's Decedent and Plaintiff were not aware that the heparin Plaintiff's Decedent received was contaminated, that it resulted in her injuries and death, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such.

213. Plaintiff and Plaintiff's Decedent did not discover, nor did they have reason to discover, that the heparin that Plaintiff's Decedent was given was contaminated and/or that Defendants' failures described herein resulted in her injuries and ultimately, death, until well after the multiple recalls by Baxter in 2008.

FACTS REGARDING PLAINTIFF PAULINE WYSKIVER

214. In November of 2007, Plaintiff Pauline Wyskiver was administered heparin while at Grant Medical Center in Columbus, Ohio.

215. Upon information and belief, the heparin administered to Plaintiff Pauline Wyskiver was a contaminated heparin product manufactured by one or more Defendants.

216. Shortly thereafter, the Plaintiff began to experience and continued to experience adverse reactions consistent with the adverse reactions associated with contaminated heparin reported to and being investigated by the FDA.

217. As a direct and proximate cause of the defective heparin being administered to her, and the attendant medical symptoms and severe injury she then suffered, Plaintiff Pauline Wyskiver and her adult children, Plaintiffs Jane McClain, Sue Yount, Carol Hill and Gail Erhardt have incurred additional damages, including, but not limited to, medical and/or other economic expenses, physical and mental pain and suffering, loss of consortium, loss of enjoyment of life, and/or other damages for which Defendants are liable.

218. At the time of her injuries, Plaintiffs and their Decedent, Pauline Wyskiver were not aware that the heparin that she received was contaminated, that it resulted in her injuries, and that said contamination was caused by Defendants' acts or omissions, nor did Plaintiffs have any reason to know of such until well after the multiple recalls by Baxter in 2008.

Federal Requirements

219. With respect to heparin, Defendants, upon information and belief, have or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. Defendants' prescription drug heparin and its active ingredient, heparin API are adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

b. Defendants' prescription drug heparin and its active ingredient, heparin API are adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity fall below the standard set forth in the official compendium for heparin and such deviation is not plainly stated on its label.

c. Defendants' prescription drug heparin and its active ingredient, heparin API, violate 21 C.F.R. § 210.1 because the process by which it is manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and has the identity and strength and meets the quality and purity characteristics that it purposes or is represented to possess.

d. Defendants' prescription drug heparin and its active ingredient, heparin API, violate 21 C.F.R. § 211.165 because the test methods employed by Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

e. Defendants' prescription drug heparin and its active ingredient, heparin API, violate 21 C.F.R. § 211.165 in that the prescription drug heparin fails to meet established standards or specifications and any other relevant quality control criteria.

f. Defendants' prescription drug heparin and its active ingredient, heparin API, violate 21 C.F.R. § 310.303 in that the prescription drug heparin is not safe and effective for its intended use.

CAUSES OF ACTION

COUNTS I-IV

Defective Manufacturing/Construction (R.C. § 2307.74)

Defective Design/Formulation (R.C. § 2307.75)

Defective Warning/Instruction (R.C. § 2307.76)

Defective Due to Nonconformity with Representation (R.C. § 2307.77)

220. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

221. At all times relevant to this action, Defendants were the manufacturers, as defined at Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled heparin products and/or their pharmaceutical ingredients that were placed into the stream of commerce.

222. The heparin products were expected to and did reach the ultimate users, including Decedent, without substantial change in the condition they were sold.

223. Defendants' heparin products and their pharmaceutical ingredients in varying dosages were defective in their:

a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;

b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;

c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or

d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.

224. Specifically, Defendants' failures, which permitted defective pharmaceuticals to be placed in the stream of commerce, include, but are not necessarily limited to:

a. Defendants' failure to exercise reasonable care in the manufacture of their heparin products and/or their pharmaceutical ingredients;

b. Defendants' failure to exercise reasonable care in the inspection of their heparin products and/or their pharmaceutical ingredients;

c. Defendants' failure to exercise reasonable care in the packaging of their heparin products and/or their pharmaceutical ingredients;

d. Defendants' failure to provide any or adequate warnings about the risks and dangers associated with the use of their heparin products, as alleged herein and/or their pharmaceutical ingredients;

e. Defendants' failure to completely, accurately and in a timely fashion, disclose the adverse event reports associated with the use of their heparin products and/or their pharmaceutical ingredients;

f. Defendants' failure to conform with their representations to Plaintiffs and/or their Decedents, their medical providers and/or agents, that the heparin products and their pharmaceutical ingredients were of merchantable quality and safe for the use for which they were intended, despite their actual and/or constructive knowledge that the heparin products to be used and warranted to be, in all respects, were not fit, safe, and effective and proper for such purposes.

g. Defendants' failure to recall, withdraw, and remove their heparin products and/or their pharmaceutical ingredients from the market once they knew or should have known of the risks and dangers associated with the use thereof;

h. Defendants' failure to promptly respond to data, reports, and publications describing problems associated with their heparin products and/or their pharmaceutical ingredients by conducting adequate analysis, testing, and surveillance;

i. Defendants' failure to implement pre-marketing and post-marketing measures to notify and warn Plaintiffs and/or their Decedents, as well as their physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said heparin products and/or their pharmaceutical ingredients, and to recall the defective heparin products;

j. Defendants' failure to adequately and reasonably establish, maintain, and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients; and/or,

k. Defendants' failure to comply with and conform to all applicable legal, regulatory, and administrative approval, licensing, and import requirements for the heparin products and all component parts, including, but not limited to, the API.

225. The heparin products and their pharmaceutical ingredients were unsafe for normal or reasonably anticipated use.

226. Plaintiffs and/or their Decedents were using heparin in the manner for which it was intended and/or in a reasonably foreseeable manner.

227. Plaintiffs and/or their Decedents could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers posed by the drug.

228. As a direct and proximate result of this defective product, Plaintiffs and/or their Decedents have been injured and incurred substantial damages, including, but not limited to, the death of the Decedents, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, funeral and burial expenses, and other damages for which Defendants are liable.

229. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs and/or their Decedents, thereby entitling Plaintiffs to recover punitive

and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

230. The application of the Ohio Product Liability Act (Ohio Rev. Code § 2307.71, *et seq.*), particularly the determination of joint and several tort liability under R.C. § 2307.22, is inapplicable to the facts of this case, or, in the alternative, is unconstitutional in whole or in part based on the facts of this case.

231. A manufacturer of drugs should not be permitted, from a public policy standpoint, to contract with a cheap foreign supplier who is not subject to inspection or accountability, then fail to test for purity, use only price as a standard for purchase, and point the finger at the supplier and claim the foreigner is at fault, thereby avoiding responsibility and liability for the sale of its contaminated products and leaving the victim with no remedy for the wrong.

COUNT V
Fraudulent Misrepresentation

232. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

233. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of the heparin products described herein, owed a duty not to deceive the Plaintiffs and/or their Decedents, their health care providers and the public regarding the safety, purity, and/or effectiveness of their drug and/or its API, and the methods or steps taken by Defendants to ensure its safety, purity and/or effectiveness.

234. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio R.C. § 2307.71 *et seq.*

235. Since June of 2002, when Baxter acquired ESI Lederle (ESI), a division of Wyeth that received their heparin API from SPL and continuing on multiple occasions to the present

date, Defendants fraudulently made the specific misrepresentations described herein regarding the safety, purity, and/or effectiveness of its drug and/or its API, and the methods or steps taken by Defendants to ensure its safety, purity and/or effectiveness.

236. Defendants' fraudulent and specific misrepresentations concerning the safety, purity, and/or effectiveness of its drug and/or its API, and the methods or steps taken by Defendants to ensure its safety, purity and/or effectiveness were made and/or published publicly on multiple occasion in various forms of media, including, but not limited to, ad campaigns, television, internet sites, and promotional materials.

237. Defendants made the misrepresentations purposefully, willfully, wantonly and/or recklessly with the deliberate intent to deceive Plaintiffs, their Decedents and/or their medical providers and to cause medical providers to prescribe, and Plaintiffs and/or their Decedents to purchase and be injected with defective and/or contaminated heparin.

238. At the time of Defendants' fraudulent misrepresentations, Plaintiffs, their Decedents and their healthcare providers were unaware and ignorant of the deceptive statements and reasonably believed them to be true and relied upon them.

239. As a direct and proximate result of this conduct, Plaintiffs and their Decedents have been injured and incurred substantial damages, including, but not limited to, the death of the Decedents, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, funeral and burial expenses, and other damages for which Defendants are liable.

240. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs and/or their Decedents, thereby entitling Plaintiffs

to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNTS VI-VIII
Loss of Consortium, Survivorship and Wrongful Death

241. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

242. As a direct and proximate result of Defendants' defective heparin described herein, Plaintiffs and/or their Decedents suffered severe personal loss and suffering, and their surviving spouses and other next of kin have also suffered the loss of services, loss of financial support, loss of society including loss of companionship, care, assistance, and mental anguish, as well as medical, funeral and/or burial expenses, entitling them to compensatory and punitive damages and attorney's fees.

COUNT IX
Punitive Damages

243. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

244. Both SPL and Baxter owned and possessed equipment and procedures which could have easily detected the existence of the contaminant.

245. SPL was in fact performing the same tests from at least 2005 to determine purity and safety of heparin.

246. Other manufacturers performed either capillary electrophoresis ("CE"), nuclear magnetic resonance spectroscopy ("NMR") or similar tests to insure purity and safety.

247. These manufacturers, including LEO and Sandoz, actually discovered contaminated heparin and as a result did not use such contamination in their finished product.

248. SPL and CZSPL knowingly and purposefully failed to perform any testing for purity on the heparin API it sold to Baxter.

249. Baxter knowingly and purposefully failed to perform any testing for purity on the heparin API it used in the manufacture of heparin.

250. Other manufacturers performed purity testing on the heparin API and in doing so were able to avoid the manufacture and distribution of contaminated heparin.

251. Both Baxter and SPL knowingly and purposefully failed to take any steps whatsoever to insure the purity and safety of the supply chain.

252. Other manufacturers, such as Baxter's main competitor in the United States, APP, now known as Abraxis, took meticulous care to insure that the supply chain which provided it with API was clean, that the heparin was uncontaminated, and that the product it sold was pure.

253. The total, intentional and flagrant disregard of purity, safety, supply chain integrity, and testing of raw materials and final product by Baxter and SPL amount to a complete and utter disregard for the safety of the vulnerable consumers who required heparin for their health.

254. This willful, reckless and gross misconduct of the Defendants, and each of them, under the circumstances here, were likely to, and did in fact cause grave and serious harm, to wit, the injuries and deaths of Plaintiffs and/or their Decedents.

255. It was reasonably foreseeably and in fact known by Baxter and SPL that their reckless, willful and wanton disregard for the safety of their products would in fact most likely cause serious harm or death.

256. Baxter and SPL chose to do business in China and SPL chose to become joint venture partners with Techpool knowing full well that Techpool would not be subject to inspection, review, accountability or analysis.

257. The willful and wanton misconduct described herein was intentionally pursued by Baxter and SPL for the sole reason of increasing their profits.

258. Baxter knowingly and purposefully chose to purchase its heparin API from the cheapest available source, without regard to purity, safety, supply chain integrity, accountability or any other factor except profit.

259. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs and/or their Decedents, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for wrongful death, medical and hospital expenses, loss of income, loss of consortium, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: November 2, 2009

Respectfully Submitted,

/s/David W. Zoll
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Counsel for Plaintiffs

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all triable issues.

/s/David W. Zoll
David W. Zoll (0008548)

Counsel for Plaintiffs